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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,399	10/03/2006	Henry William Lupton	LRM-36144-A-US	4662

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EXAMINER

PANI, JOHN

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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04/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/539,399	Applicant(s) LUPTON, HENRY WILLIAM	
	Examiner JOHN PANI	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,55,57-67 and 69-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,55,57-67 and 69-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pg. 5 "Claim Rejections - 35 USC §112" , filed 1/19/2010, with respect to claim 56 have been fully considered and are persuasive. The rejection of 7/17/09 has been withdrawn.
2. Applicant's remaining arguments filed 1/19/2010 have been fully considered but they are not persuasive. In response to Applicant's assertion that the outstanding rejection is "substantially identical to the §102(e) over Osawa rejection... mailed 8/26/2008", the Examiner respectfully disagrees and notes that the detailed rejection of 7/17/09 maps out the various claimed structures to the Osawa reference in a new manner, and that in this new rejection, the particular embodiment relied upon was changed to that of Fig. 8 from the embodiment of Fig. 5, and claim terms were interpreted in new ways. Further, the Examiner submits that these changes as written in the rejection of 7/17/09 explain how the embodiment of Fig. 8 was applied in a manner sufficient for Applicant to understand the Examiner's basis of rejection. Furthermore, in response to Applicant's assertion that Osawa does not teach "the reinforcing member...extending...to a location on the distal portion axially spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion", the Examiner respectfully disagrees, and notes that as detailed in the rejection of 7/17/09, the middle stepped section of Fig. 8-A is now interpreted as the "reinforcing member", while the section of lower height to its left in Fig. 8-A is now

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interpreted as the “guide portion”, and that this middle section clearly extends to and terminates at a point axially spaced apart from the most distal end of the distal portion and thereby provides a defining edge to the guide portion/left-most step, and that the distal end of the device provides an additional defining edge to this guide portion/left-most step, and that therefore Osawa does in fact disclose the claimed invention in the manner described in the Office Action of 7/17/09.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 54, 55, 57-67 and 69-77 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 7,083,577 to Osawa et al. (“Osawa”).

5. Osawa teaches:

In reference to Claim 70

A guide wire (1) for use in a surgical or other procedure for accessing a remote site in a body of a human or animal subject (col. 1 lines 5-7), the guide wire defining a longitudinally extending axis (see Fig. 10), and terminating at one end in a proximal portion (proximal end in Fig. 10), and at an opposite end in a distal portion (23) for

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accessing the remote site, the distal portion having a proximal end and a distal end and being of rectangular transverse cross-section (see Fig. 8C) defining a pair of opposite major flat surfaces (the thin, flat surfaces that angle inward in Fig. 8B and are shown face on in Fig. 8C), joined by a pair of opposite minor surfaces (the top surface shown in Fig. 8B, and matching bottom surface), and terminating adjacent the distal end thereof in a guide portion (portion of 23 from left --i.e. distal-- end as depicted in Figs. 8B,C to the beginning of middle step of the three stepped portions), the guide portion being adapted to be shaped to a desired curved configuration for facilitating guiding of the guide wire into a branched vessel of the subject (see col. 7 lines 31-40), and an elongated reinforcing member (middle step) located on the distal portion of the guide wire for minimizing axial twisting of the distal portion between the proximal end of the distal portion and the guide portion thereof (see col. 4 lines 50-65), the reinforcing member having a proximal end and a distal end and extending along one of the flat major surfaces of the distal portion of the guide wire from the proximal end of the distal portion to a location on the distal portion axially spaced apart from the distal end of the distal portion to define with the distal end of the distal portion the guide portion (see Figs. 8A-C).

In reference to Claim 54

A guide wire as claimed in claim 70 (see above) in which the major flat surfaces of the distal portion define a central major plane located midway between the major surfaces, and the minor surfaces of the distal portion define a central minor plane located midway between the minor surfaces (see Figs. 8A-8C).

In reference to Claim 55

A guide wire as claimed in claim 70 (see above) in which a reinforcing member is located on each major flat surface (Figs. 8A-8C).

In reference to Claim 77

A guide wire as claimed in claim 70 (see above) in which the reinforcing member extends from the major flat surface of the distal portion of the guide wire to a longitudinally extending edge, the longitudinally extending edge extending from the proximal end of the reinforcing member to the distal end of the reinforcing member (see Fig. 8A).

In reference to Claim 57

A guide wire as claimed in claim 54 (see above) in which the reinforcing member extends parallel to the central minor plane (i.e. radially).

In reference to Claim 58

A guide wire as claimed in claim 54 (see above) in which the reinforcing member extends at an angle greater than zero degrees to the central minor plane (the raised surfaces have extensions at various non-zero angles with respect to the central minor plane).

In reference to Claim 59

A guide wire as claimed in claim 77 (see above) in which the reinforcing member defines opposite longitudinally extending sides (portions of step visible in Fig. 8B), the opposite longitudinally extending sides of the reinforcing member terminating along the longitudinally extending edge of the reinforcing member (Fig. 8A).

In reference to Claim 60

A guide wire as claimed in claim 59 (see above) in which the opposite longitudinally extending sides of the reinforcing member are parallel to each other (note that the stepped portions found on the two sides could be considered a single reinforcing member, and their opposite longitudinally extending sides are parallel, see Fig. 8B).

In reference to Claim 61

A guide wire as claimed in claim 70 (see above) in which the reinforcing member is integrally formed with the distal portion (see Fig. 8A) of the guide wire.

In reference to Claim 62

A guide wire as claimed in claim 70 (see above) in which the distal portion of the guide wire extends through a sleeve (3), and a first securing means (4) at the distal end thereof secures the distal portion to the sleeve, the first securing means defining the distal end of the guide wire (see Fig. 10).

In reference to Claim 63

A guide wire as claimed in claim 62 (see above) in which the first securing means is shaped to form a dome shaped distal end of the guide wire (see Fig. 10) for facilitating passage of the guide wire smoothly through a vessel of the subject.

In reference to Claim 64

A guide wire as claimed in 62 (see above) in which the guide portion is located between the reinforcing member (see Fig. 8A) and the first securing means (see Fig. 10)

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In reference to Claim 65

A guide wire as claimed in claim 62 (see above) in which the first securing means comprises a solder joint, an adhesive joint, or a brazed joint (see col. 7 lines 58-60).

In reference to Claim 66

A guide wire as claimed in claim 62 (see above) in which the sleeve extends in a proximal direction beyond the proximal end of the distal portion along a portion of the guide wire (see Fig. 10), and that a proximal end of the sleeve is secured to the guide wire by a second securing means that comprises an adhesive joint, solder joint, or a brazed joint (see col. 7 lines 55-60).

In reference to Claim 67

A guide wire as claimed in claim 70 in which the guide wire is substantially torsionally rigid between the distal portion and the proximal portion of the guide wire for minimizing axial twisting of the guide wire between the proximal portion and the guide portion (see col. 4 lines 50-65).

In reference to Claim 69

In combination a catheter (see col. 1 lines 5-7) and the guide wire as claimed in claim 70 (see above).

In reference to Claim 71

A guide wire as claimed in claim 70 (see above) in which the reinforcing member extends in a generally axial direction (see Fig. 8A).

In reference to Claim 72

A guide wire as claimed in claim 70 (see above) in which the major flat surfaces of the distal portion converge towards each other towards the distal end of the distal portion (see Fig. 8B).

In reference to Claim 73

A guide wire as claimed in claim 54 (see above) in which the reinforcing member coincides with the central minor plane (Fig. 8A).

In reference to Claim 74

A guide wire as claimed in claim 70 (see above) in which the reinforcing member extends adjacent one of the minor surfaces (see Fig 8A).

In reference to Claim 75

A guide wire as claimed in claim 59 (see above) in which the opposite longitudinally extending sides of the reinforcing member converge towards the longitudinally extending edge of the reinforcing member for defining the longitudinally extending edge as a longitudinally extending ridge (see Fig. 8A, viewed head on, the step is a ridge).

In reference to Claim 76

A guide wire as claimed in claim 59 in which the longitudinally extending edge of the reinforcing member converges towards the distal portion adjacent the distal end of the reinforcing member (see Fig. 8A).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 3/29/10

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736